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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

09065.0007-00000

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on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Application Number

10/790,024

Filed

March 2, 2004

First Named Inventor

Robert Frederick VEASEY et al.

Art Unit

3763

Examiner

Laura A. BOUCHELLE

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

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applicant/inventor.



Signature

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.

Christopher S. Weber

Typed or printed name

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attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

June 27, 2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

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\*Total of 1 form is submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT  
Customer No. 22,852  
Attorney Docket No. 09065.0007-00000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

**Robert Frederick VEASEY et al.**

Application No.: 10/790,024

Filed: March 2, 2004

For: **DRIVE MECHANISMS SUITABLE  
FOR USE IN DRUG DELIVERY  
DEVICES**

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) Group Art Unit: 3763  
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) Examiner: Laura A. Bouchelle  
)  
) Confirmation No.: 9740  
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)  
)

**Mail Stop AF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicants request a pre-appeal brief review of the rejections in the Final Office Action mailed December 31, 2007, the period for response extending through June 30, 2008, by a petition for an extension of time of three months filed concurrently herewith. This Request is being filed concurrently with a Notice of Appeal, in accordance with the Official Gazette Notice of July 12, 2005.

A pre-appeal brief review of the rejection set forth in the Final Office Action is proper because: (1) the application has been at least twice rejected; (2) Applicants have concurrently filed a Notice of Appeal (prior to filing an Appeal Brief); and (3) this Pre-Appeal Brief Request for Review is five (5) or less pages in length and sets forth legal or factual deficiencies in the rejections. See Official Gazette Notice, July 12, 2005.

In the Final Office Action mailed December 31, 2007, the Examiner maintained the rejections made in the Non-Final Office Action mailed April 11, 2007. Claims 1-7 and 9-19 are pending in this application.

**REMARKS<sup>1</sup>**

**I. REJECTION OF CLAIMS 1-6, 9-14, and 16-19 UNDER § 102(b)**

Applicants respectfully traverse the rejection of claims 1-6, 9-14 and 16-19 under 35 U.S.C. § 102(b) as being anticipated by Hjertman et al. (5,679,111) ("Hjertman").

Independent claim 1 recites a drive mechanism comprising, among other things, "a piston rod . . . which is threadedly engaged with the internal thread of the housing . . . a dose dial sleeve . . . and a clutch means located between the drive sleeve and the dose dial sleeve."

The Office Action of December 31, 2007 alleges that:

Hjertman discloses a device for dosing a liquid preparation comprising a housing 3 having internal and external threads, a piston rod 12, a coupling 7, a dose dial sleeve 2, a drive sleeve 17, and a clutch sleeve 15. See Fig. 1. Hjertman inherently discloses the steps of providing the drive mechanism above. The device may be used to inject a patient with insulin (Col. 3, lines 16-17).

(December 31, 2007, Office Action, p. 2). The piston rod of claim 1 includes the limitation that the piston rod is "threadedly engaged with the internal thread of the housing," and the specification of the instant application defines "threadedly engaged" to mean the interlocking of helical threads of components. (Specification, p. 4). The Office Action alleges that piston rod 12 of Hjertman is locked in place with locking lugs 14, and lugs 14 are threadedly engaged to sleeve 3. (December 31, 2007, Office

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<sup>1</sup> The Final Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified herein, Applicants decline to automatically subscribe to any statement or characterization in the Final Office Action.

Action, p. 3). Because piston rod 12 of Hjertman is only indirectly coupled to sleeve 3 it cannot also be threadedly engaged to sleeve 3. The only component that piston rod 12 is threaded with is screw 28 of stopping device 29, and this cannot be described as “a housing having an internal and external thread,” as recited in claim 1. For at least these reasons, Hjertman does not teach, or even suggest, having “a piston rod . . . which is threadedly engaged with the internal thread of the housing.”

Notwithstanding the above discussion, which is sufficient for withdrawal of the rejection, claim 1 further recites “a dose dial sleeve, which is threadedly engaged with the external thread of the housing.” The Office Action alleges that front sleeve 2 of Hjertman corresponds to the dose dial sleeve. However, Hjertman discloses that the front sleeve 2 is one of three components combined to hold an injection cartridge. (Hjertman, col. 4, ll. 11-18). Furthermore, Hjertman discloses that screw 28 and stopping device 29 combine to determine the dose. (Hjertman, col. 5, ll. 31-39). For at least these reasons, Hjertman does not teach or even suggest having “a dose dial sleeve, which is threadedly engaged with the external thread of the housing.”

Notwithstanding the above discussion, which is sufficient for withdrawal of the rejection, claim 1 still further recites “a clutch means located between the drive sleeve and the dose dial sleeve.” The Office Action alleges that the stalks 15 of Hjertman corresponds to the clutch means. (December 31, 2007, Office Action, p. 3). As in initial matter, the stalks 15 of Hjertman are not “between the drive sleeve and the dose dial sleeve.” As discussed above, the Office Action alleges that the front sleeve 2 corresponds to the dose dial sleeve, and the Office Action also alleges that actuating sleeve 17 corresponds to the drive sleeve. (December 31, 2007, Office Action, p. 2).

The Office Action further alleges that stalks 15 are on the interior of both front sleeve 2 and actuating sleeve 17 and therefore it is between them because it is within them.

(December 31, 2007, Office Action, p. 2). It can best be seen in Figs. 4 and 5 that stalks 15 are located within front sleeve 2, and front sleeve 2 is located within actuating sleeve 17. So stalks 15 cannot be located between front sleeve 2 and actuating sleeve 17. Furthermore, claim 1 recites:

“a clutch sleeve . . . which

a) when the dose dial sleeve and the drive sleeve are decoupled by the clutch means, rotation of said dose dial sleeve with respect to the drive sleeve is allowed; and

b) when the dose dial sleeve and the drive sleeve are coupled by the clutch means, rotation of the dose dial sleeve with respect to the drive sleeve is prevented.”

Hjertman discloses that stalks 15 and lugs 14 prevent longitudinal movement of the piston rod, not rotation of the dose dial sleeve. (Hjertman, col. 4, l. 65 - col. 5, l. 3). For at least these reasons, Hjertman does not teach or even suggest “a clutch means located between the drive sleeve and the dose dial sleeve.”

Accordingly, for at least the reasons presented above, Hjertman cannot anticipate independent claim 1. Therefore, Applicants respectfully request the withdrawal of the rejection of independent claim 1 and the allowance of independent claim 1. Claims 2-6, 9-14, and 16-19 depend from claim 1 and are at least patentable for this reason. Furthermore, these dependent claims recite more specific features than the independent claim and are additionally patentable for this reason. Applicants respectfully request the withdrawal of the rejection of these dependent claims and the allowance of these dependent claims.

II. **REJECTION OF CLAIMS 7 and 15 UNDER § 103(a)**

Applicants respectfully traverse the rejection of claims 7 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Hjertman in view of Slate et al. (US 2002/0167499) ("Slate").

As discussed above, Hjertman does not disclose or suggest all of the elements of claim 1, and claims 7 and 15 depend from claim 1. Slate does not compensate for the deficiencies of Hjertman. Therefore claims 7 and 15 are patentable for this reason. Additionally, these dependent claims recite more specific features than the independent claim and are additionally patentable for this reason. Applicant respectfully requests the withdrawal of the rejection of these dependent claims and the allowance of these dependent claims.

**CONCLUSION**

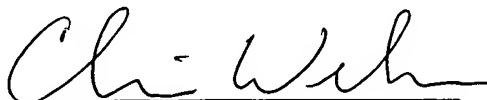
In view of the above, Applicants respectfully request that the rejections be withdrawn and the claims allowed.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: June 27, 2008

By:   
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